UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	(Subcategory Docket: 06-11337)
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 07-CV-11618-PBS	)	Judge Patti B. Saris
	)	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES INC.'S RESPONSE TO VEN-A-CARE'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Dated: November 2, 2009

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INTRODUCTION

Ven-A-Care – a former home infusion pharmacy that now exists solely as a professional *qui tam* litigant – has brought a False Claims Act ("FCA") action limited to Medicaid claims on the oral, patient-administered Erythromycin ("Ery") antibiotics sold by Abbott's Pharmaceutical Products Division ("PPD").[1] The United States has declined to intervene.[2] Now moving for summary judgment, Ven-A-Care asks this Court to undertake an impermissible, indeed impossible, task – to resolve as a matter of law, on an element-by-element basis, this FCA case, on a record filled with disputed facts. Ven-A-Care also asks the Court to bar evidence about the government payor's understanding and expectations with respect to price reporting and the federal government and the state Medicaid programs' use of price spreads to fulfill their own public policy goals. Ven-A-Care's motion should be denied because it is procedurally and substantively insufficient to support a summary judgment ruling.

In the first instance, Ven-A-Care's motion is improper under Rule 56 because it seeks piecemeal summary judgment on elements and evidence rather than on an entire claim. *See* Fed. R. Civ. P. 56(c); *Tiger Petroleum v. Alliot*, 319 B.R. 225, 233-34 (N.D. Okla. 2004); *S.E.C. v. Thrasher*, 152 F. Supp. 3d 291, 295 (S.D.N.Y. 2001). If the Court does not deny the motion for this reason, the Court should still deny the motion entirely if it finds the motion inadequate as to even one element. *See In re: Hartmarx Securities Litig.*, No. 01 C 7832, 2003 WL 22757748, at *6 (N.D. Ill. Nov. 20, 2003).

[1] Throughout this brief, "Abbott" or "Abbott PPD" refers only to Abbott's PPD, not Abbott's former Hospital Products Division ("HPD"), which is the subject of the DOJ's Case No. 06-CV-11337-PBS.

[2] Abbott has filed a motion to dismiss this case based on the FCA's public disclosure bar. The parties are briefing this motion and have agreed to have it heard before any summary judgment motion.

The motion also fails because the record is replete with genuine disputes of material facts and other, undisputed facts that clearly do not support the motion. For example, the record shows the following:

- Abbott PPD's Erys were originally innovator, branded drugs. As it does for all of its branded drugs, Abbott PPD sold the branded Erys at List Prices and WACs. When faced with generic erythromycin competition, Abbott set discounted contract prices solely to compete with the lower-priced generics. Abbott maintained the List Prices and WACs for legitimate business reasons and with no consideration for how those prices might effect payment rates set by state Medicaid programs. Indeed, Abbott PPD continued to make substantial sales of its Ery products at the List Prices and WACs.

- The Ery spreads between the AWPs and the average transaction costs (about $3 per prescription) were well within the federal and state governments' expectations, and even *shrunk* during the relevant period alleged in the Complaint (1994-2007). Indeed, the spreads were not only known, but employed, to further Medicaid program policy objectives; for example, the $3 spreads were less than, and used to subsidize, the difference between pharmacies' dispensing costs and the Medicaid dispensing fees.

- Abbott PPD accurately reported the List Prices and WACs for its Ery products to the pricing compendia, precisely as the compendia instructed and as Abbott personnel legitimately understood that they were supposed to; Abbott PPD did not set AWPs and refused to verify them for the compendia.

- Abbott PPD did not "market the spread" on its Ery products.

- Indeed, marketing the spread on the Erys would have been futile because the Medicaid payments were not based on AWP, and were capped by FULs and state MACs, which often were set based on considerations other than reported prices.

Even Ven-A-Care concedes that there are issues of fact when it hedges: "there is *little* factual disagreement" (VAC Mem. at 1); "Abbott *essentially* admits" (*id.* at 12); "To the extent any statement of fact herein is genuinely disputed, Plaintiff reserves the right to argue that the disputed fact is not material" (VAC SOF, Intro (emphases added).) These asides are significant concessions that Ven-A-Care is not in a position to overcome the real factual disputes that surround every element of Ven-A-Care's FCA claims.

Similarly doomed is Ven-A-Care's request for summary judgment on what it (incorrectly) characterizes as "affirmative defenses," including whether the state Medicaid programs knew

about and intentionally chose to pay the spread on Ery products for policy reasons, such as the legal mandate to ensure equal access to care for Medicaid patients, the need to compensate for inadequate dispensing fees, or the desire to encourage pharmacies to dispense generic drugs. The facts surrounding the various state programs' informed policy choices impact every element of Ven-A-Care's claims, and they must be resolved by the trier of fact at trial.

FACTS

As demonstrated below and in Abbott's response to Ven-A-Care's Rule 56.1 statement of facts ("RSOF") and Abbott's additional statement of facts ("SOAF"), genuine disputes about material facts, and about the inferences to be drawn from any agreed facts, permeate all arguments raised in Ven-A-Care's motion.

A. Price Competition From Generic Manufacturers, Motivated Abbott PPD To Use Contracts And Terms To Offer Discounts Below The List Prices.

Abbott PPD originally developed, priced, marketed, and sold the Erys as brand name drugs. (SOAF ¶ 1.) As branded drugs, the Erys were sold at List Prices and WACs. (*Id.*) Over time, the Ery formulations lost their patent protection, and other manufacturers began selling generic versions at lower prices. (*Id.* ¶ 2.) In order to compete with the generic manufacturers and to maintain market share, Abbott began offering terms and contracts for the Erys, under which customers could obtain discounts and rebates in exchange for meeting certain volumes and share requirements, providing sales data to Abbott, and other considerations. (*Id.* ¶ 3.) The sales at the discounted contract prices were reflected in the Average Manufacturer's Prices ("AMPs") that Abbott PPD reported directly to the U.S. government on a quarterly basis during the entire claims period alleged in this case. (*Id.* ¶ 25.)

B. Abbott PPD Made Substantial Sales Of Ery At The List Prices And WACs.

One of the few undisputed facts in this case is that, even during the alleged claims period, Abbott PPD did indeed sell the Erys at the List Prices and WACs that Abbott PPD reported to the compendia. Customers that did not have an Ery contract and purchased less than a case of Ery were charged List Price. (SOAF ¶ 6.) Customers that purchased at least a case but less than $500 of Ery were charged WAC. (*Id.* ¶ 7.) Starting in July 2003, Abbott eliminated the discounted price available to customers purchasing $500 or more of Ery product (the so-called Base Deal Price[3]), so all wholesalers were invoiced WAC. (*Id.* ¶ 10.) Although Ven-A-Care tries to minimize the fact that sales occurred at these reported prices, the sales data show that these sales were real and significant. For example, 17% of direct customers paid List Prices or WACs 100% of the time during the relevant fourteen-year period, and even 34% paid those prices at least 25% of the time. (*Id.* ¶ 11.)

C. Abbott PPD Set Prices For The Erys Based On Legitimate Business Reasons And With No Regard For Government Payments.

Abbott set the Erys' contract prices, List Prices, and WACs based on business and market factors, and without regard to government payments under Medicaid (or any other third-party reimbursement spreads). (SOAF ¶ 12.) Abbott has had several legitimate business reasons to maintain List Prices and WACs higher than the discounted contractual prices. Sales at List Prices and WACs are high profit sales. (*Id.* ¶ 13.) In addition, the List Prices and WACs have been the starting point under which various tiers of discounted contract prices were offered. (*Id.* ¶ 14.) The higher List Prices and WACs also encourage customers to enter a contract under

[3] Base Deal Price was another price available if a wholesaler met volume terms – $500 of Ery on a single invoice. (SOAF ¶ 8.) Contrary to Ven-A-Care's representation, Abbott PPD did not provide Base Deal Pricing to wholesalers that had not met the terms, and Base Deal Prices were not set at a "fraction" of WACs. For several Ery NDCs, the Base Deal Price was the same as the WAC, and for most others the difference was in the 2% to 30% range. (*Id.* ¶ 9.) Abbott PPD eliminated Base Deal Prices in 2003 when (contrary to Ven-A-Care's assertion) many of the contract prices to pharmacies rose to equal or exceed the Base Deal Prices to wholesalers. (*Id.* ¶ 8.)

which they would provide Abbott services such as valuable sales information. (*Id.* ¶ 15.) The List Prices and WACs increased only five times during the claims period, the result of inflationary increases on all PPD products. (*Id.* ¶ 16.) In fact, these prices increased well slower than inflation. (*Id.*) Abbott set the lower contract prices only to stay competitive with the generic manufacturers. (*Id.* ¶¶ 3-4.)

D. Abbott PPD Personnel Responsible For Setting And Reporting Prices Were Informed And Understood That Abbott Was Supposed To Report Its List Prices And WACs To The Compendia.

Abbott PPD reported to the pricing compendia a List Price and WAC at the launch of a product and whenever the product's List Price or WAC changed. (SOAF ¶ 24.) Every Abbott PPD employee deposed on this issue testified that he or she thought that Abbott was reporting the prices that the pricing compendia wanted and in accordance with Abbott's use and understanding of those terms. (SOAF ¶¶ 27, 31.) For example, Joseph Fiske, who was the Director of Pricing and Planning, testified:

> The information that we reported to the data agencies was our WAC and our list price. Any changes to our WAC and list price, we did so in good faith with the expectation that that was the information we should be providing. Nobody told us to do anything differently than that, including Kay Morgan who certainly had the opportunity because she knew what our practices were.

(*Id.* ¶ 27(a).)[4] April Gerzel, the only Abbott PPD employee whom Ven-A-Care deposed in this case who had direct communications with the pricing compendia, testified that she understood that the pricing compendia were requesting that Abbott report its List Prices and WACs. (*Id* ¶ 27(b).)

[4] Kay Morgan worked at Abbott from 1975 to 1999 and then went to First DataBank as Manager of Editorial Services where she was responsible for the pricing information First DataBank published until 2005. (SOAF ¶ 28.) As such, she was familiar with both Abbott's pricing practices and the information that First DataBank intended to obtain from manufacturers. (*Id.*)

Abbott's understanding is perfectly in keeping with the instructions it received from the compendia. For example, in 1995, Red Book instructed pharmaceutical manufacturers to "send . . . WAC pricing," which it defined as "the manufacturer's quoted list price to wholesale distributors *and does not reflect any deal terms or specialized contract pricing*." (SOAF ¶ 20 (emphasis added).) That is exactly what Abbott PPD reported.[5]

Abbott PPD also reported List Prices (usually in columns labeled "List Price") consistent with how that term was understood in the industry (i.e., an advertised price not including any discounts. (*Id.* ¶ 24.)

Abbott PPD did not set AWPs for the Ery drugs. (SOAF ¶ 32.) At times, Abbott personnel put "est. AWP" on some forms based on an understanding of an observed mathematical relationship between WAC and AWP, but they did not believe that Abbott was controlling AWP. To the contrary, Abbott PPD personnel understood that the compendia determined their formula to set AWPs based on surveys of wholesalers. (*Id.* ¶ 29.) Accordingly, Abbott refused to report AWPs or to verify their accuracy. (*Id.* ¶ 33.)

E. Abbott Did Not Market Any Spread On Ery Drugs.

As it did with its pricing practices, Abbott sold its Ery products without regard for the so-called "spread." Each of the Abbott employees deposed about this issue unequivocally denied marketing the spread or setting prices in order to do so. (SOAF ¶ 18.)[6] Finding no evidence to

[5] This definition is also consistent with how the industry has understood WAC and how Congress defined the term in the Medicare Modernization Act of 2003 (the only instance of the government defining WAC): "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not *including prompt pay or other discounts, rebates or reductions in price*." (*Id.* ¶ 22 (emphasis added).)

[6] Ven-A-Care's claim that Abbott PPD marketed the spread rests on a single document, a draft sheet that showed the AWP and "your low price," and the theory that other parties marketed the spread for Abbott. First, Ven-A-Care touts this document (i) without proof that the "low price" column was ever completed or that the document was ever disseminated to any customer and (ii) in contradiction of the Abbott PPD personnel's undisputed testimony that this document had nothing to do with marketing the spread and would have only alerted customers that they were getting a discount off of list prices. (SOAF ¶ 19.) Furthermore, Abbott's pharmaceutical marketing expert in this case has opined that, if Abbott PPD were indeed marketing the spread, he would expect far more evidence than

support its pleading that Abbott "actively promot[ed] [the] spreads" "as a marketing tool," Ven-A-Care downshifts to a theory that the spreads somehow marketed themselves. This rhetorical flourish, albeit convenient for Ven-a-Care because it requires them to prove nothing, makes no sense with respect to the Erys because, among other reasons and as explained in Section F below, Medicaid payments for the Erys typically were capped by FULs and MACs. (*Id.* ¶¶ 38, 47-48.) Thus, a pharmacy could not increase its Medicaid payment by submitting a claim for an erythromycin with a higher AWP. (*Id.*) In other words, marketing the spread would have been futile.

F. The State Medicaid Programs Did Not Base Payments For The Ery Drugs On The Reported Prices, And Used Known Spreads To Help Run The Programs.

1. Medicaid payments for the Erys were based on FULs and MACs that were not calculated from the reported prices for the Erys.

During the alleged claims period, there were FULs and many state MACs capping Medicaid payments for multisource, oral erythromycins including the Erys. (SOAF ¶¶ 38, 47-48.) Ven-A-Care presents no evidence that these FULs and MACs were based on the reported Abbott PPD Ery prices (its expert admits that he did nothing to establish such a link), and the record indicates that they were not. (*Id.* ¶¶ 46, 49.) First of all, federal regulation instructed CMS to set FULs at 150 percent of the lowest published price for the least costly generic equivalent. (*Id.* ¶ 39) For the Erys, the lowest published price was never the AWP, so AWPs are immaterial. Second, CMS and the states often overlooked other reported prices in setting the

(continued…)

what Ven-A-Care has proffered. (*Id.* ¶ 18.) Of course, Ven-A-Care's expert disagrees, but this battle of the experts merely raises disputed facts that preclude summary judgment. Second, Ven-A-Care's claim that "Abbott worked with other participants in the drug industry, such as wholesalers and retail buying groups, to ensure that information about Abbott's published prices was communicated to customers, allowing them to calculate the spread they would receive" is unsupported (*see* RSOF ¶¶ 37-41) and contradicted by Abbott's uncontraverted testimony that it did not work with, or authorize, anyone to market the spread. (SOAF ¶¶ 18-19.)

FULs and MACs. CMS disregarded published prices and set higher FULs in response to feedback from the pharmacy community or to assure Medicaid patients' access to pharmaceuticals. (*Id.* ¶¶ 40-45.) Individual state Medicaid programs also used a variety of information and formulae to establish MACs for many generic drugs, including erythromycins. (*Id.* ¶ 49-50.) Such information included: invoices provided by pharmacies; direct surveys of pharmacies; and review of wholesaler catalogs and price lists, among other pricing sources. (*Id.* ¶ 49.) As described in Section 3 below, many states considered pharmacies' input and policy considerations, such as access issues, when setting MACs and the formulae to calculate EACs.

2. Federal and state payors were well aware of the spreads between the Erys' AWPs and average net transaction prices.

Throughout the 1980s and 1990s, there were public disclosures about price spreads, including specific disclosures relating to Abbott and the Erys. For example, twenty-five years ago in 1984, the HHS-OIG issued a report titled "Medicaid—Limitation on payment for drugs," which noted that "AWP means non-discounted list price" and that "[p]harmacies purchase drugs at prices that are discounted significantly below AWP or list price." (SOAF ¶ 42.) The report analyzed the differences between AWP and pharmacy acquisition costs for a select number of drugs, including EES 400®, an Abbott Ery drug at issue in this case. (*Id.*) The report found that the *70th percentile* of audited prices for EES 400® was $16.49 while the published AWP was $21.95 – a spread of 33%. (*Id.*) The report further found that the median price paid for EES 400® in Massachusetts was $14.06 – a spread of 56%.[7] (*Id.*)

In July 1992, the Energy and Commerce Committee of the U.S. House of Representatives held a hearing concerning proposed bills to establish limits on certain drug prices. (SOAF ¶ 66.)

[7] The spreads represented in Ven-A-Care's Complaint are each exaggerated by 100%. For example, based on Ven-A-Care's method of calculating spread in the Complaint's Exhibit A, even if a drug's AWP is only 5% more than the "relator's cost," Ven-A-Care would claim that drug has a 105% spread. For consistency and to enable valid comparisons, this brief will utilize a proper calculation of spread ((AWP-AAC)/AAC or (AWP/AAC)-1.0).

As part of that hearing, price lists showing the discrepancies between AWP and contract prices available to certain providers were introduced into the public record. (*Id.*) Several versions of Abbott's Erys at issue in this case were on that list, including EES 400® TABs, EES® 200 liquid, EES 400® liquid, Ery-TAB® 250 mg tabs, Ery-TAB® 333 mg, and Ery-TAB® 500 mg. (*Id.* ¶ 67.) The price lists show discounts for these drugs ranging from AWP-56% to AWP-86% (spreads of 127% to 614%). (*Id.*)

In August 1997, the HHSC's Office of Inspector General issued a comprehensive report that concluded that pharmacies pay an average of 42.5% less than AWP for generic drugs, such as Abbott's Ery drugs, dispensed to Medicaid beneficiaries. (SOAF ¶ 68.) This report publicly disclosed that generic drugs, which includes the Erys, on average, had spreads of approximately 74%, which is similar to the spreads that Ven-A-Care alleges in this case. The OIG work papers created in connection with the report specifically show that the report included Abbott's Ery-TAB.® (*Id.*)

In 1999, Myers and Stauffer issues a report, "A Survey of Dispensing and Estimated Acquisition Costs in the State of Wyoming," with included Ery-Tab® and showed average acquisition cost of multi-source drugs with MACs had an average discount of 73.7% off AWP. (SOAF ¶ 74.) (For other examples of public disclosures about Erys and generic drugs, see *id.* ¶¶ 62 - 80.)

Indeed, by 2001, as this Court has recognized in another AWP case regarding branded drugs, "there was a perfect storm of information that reflected the size of the spreads, largely because of the compelling information collected by the HHS Office of Inspector General ('OIG'). In addition, the press began to report on the rampant abuse of the AWP system." *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 ,40 (D. Mass 2007). Armed with (i) these public disclosures, (ii) the AMPs that Abbott was reporting to CMS and (iii) Ven-

A-Care's complaint and Section 3730(b)(2) disclosures provided in 2000 and 2001, CMS and the state Medicaid agencies were fully cognizant of, and indeed expected, the Ery spreads well earlier, but certainly no later, than 2001.

The Medicaid program's knowledge of these spreads continued to be confirmed and grow even after 2001. In March 2002, the OIG published another acquisition cost report, which found a "significant difference between pharmacy acquisition cost for generic drugs and AWP," equal to, on average, AWP-65.93%. (SOAF ¶ 77.) In September 2002, the OIG released another report, which found that multisource drugs with established FULs were purchased on average at AWP-72.1%. (SOAF ¶ 78.)

3. With full knowledge, the government paid spreads on Medicaid claims to meet policy goals.

Despite extensive knowledge about the relationship between AWPs and actual acquisition costs and about the Ery "spreads," the Medicaid programs have continued to use AWP in their payment formulae, to use discounts off AWP in their EAC formulae that are significantly less than those suggested in OIG and other government reports, and to pay spreads for ingredient costs. Federal and state Medicaid witnesses uniformly admitted that states knowingly paid more than average acquisition cost for multi-source drugs such as the Erys in order to further policy goals. (SOAF ¶¶ 81, 92, 94-96.) For example, states paid the spreads to meet the federal mandate that Medicaid patients have access to pharmaceuticals equal to the general population's access. (*Id.* ¶ 85-86.)

States specifically permitted ingredient cost spreads to subsidize inadequate dispensing fees ("cross-subsidization"). While most state Medicaid programs paid dispensing fees between $3 and $5, the pharmacies' dispensing costs that dispensing fees were supposed to cover have uniformly been found to be in the $9-12 range – i.e., inadequate by around $6-7. (SOAF ¶¶ 88-

90.) State Medicaid programs recognized this inadequacy, particularly when their dispensing fees failed to keep pace with inflation (many states failed to adjust dispensing fees at all during the fourteen-year claims period). (*Id.* ¶ 91.) Pharmacies specifically looked to the extra ingredient cost payments to subsidize the insufficient dispensing fees. (*Id.* ¶ 94.) Faced with tremendous pressure from pharmacists to make them whole and to provide some profit, the Medicaid programs cross-subsidized the dispensing fees with the ingredient cost payments in order to keep pharmacies in the Medicaid program and to meet the federal equal access requirement. (*See, e.g.*, SOAF ¶ 94 (1993 U.S. GAO report: "HCFA and state Medicaid officials agreed that pharmacies must often use excess Medicaid reimbursements to cover their dispensing costs."); *id.* ¶ 93 (Del.: "[P]roviders relied upon a margin on ingredient costs . . . [to] supplement per the inadequate dispensing fee" that had been frozen); *id.* ¶ 94(b) (Ill.: "We also expect arguments that dispensing fees should be increased to compensate for some of the revenue lost because of reductions in AWP."); *id.* ¶ 94 (Minn.: "[W]e've always kept [the dispensing fee] below what we think the true cost of dispensing is to make up for the fact that there is some money being made on the ingredient side."); *see also id.* ¶ 44.) Notably, the claimed spread per Ery prescription – about $3 (SOAF ¶ 11.) – was no greater than the amount needed to cross-subsidize the inadequate pharmacy dispensing fees.

States also permitted margins to encourage pharmacies to dispense generics. (SOAF ¶ 96.) For example, to support its policy decision to pay an average 44% profit margin on generics, Illinois reasoned: "This profit disparity is another way this rule promotes the dispensing of generics over brand names." (*Id.*¶ 96(b).)

STANDARD

To award summary judgment to Ven-A-Care, the Court must find no genuine issue of material fact when viewing the evidence "in the light most favorable to the non-moving party"

and making every reasonable inference from the evidence in Abbott's favor. *Barbour v. Dynamics Research Corp.*, 63 F.3d 32, 36 (1st Cir. 1995); *see also Sanchez v. Alvarado*, 101 F.3d 223, 227 (1st Cir. 1996).

Moreover, although Ven-A-Care appears to ask this Court for summary judgments on an element-by-element basis, nothing in Rule 56 envisions such a cafeteria-style ruling. *See In re Pharm. Indus. Avg. Wholesale Price Lit.*, No. 06-11337-PBS, Mot. Hrg. at 5-6 (D. Mass. Oct. 20, 2009); *Tiger Petroleum v. Alliot*, 319 B.R. 225, 233-34 (N.D. Ok. 2004); *S.E.C. v. Thrasher*, 152 F. Supp. 3d 291, 295 (S.D. N.Y. 2001). If the Court chooses to proceed at all, the entire motion must be denied if the Court finds, as it should, that summary judgment is improper on any single element of Ven-A-Care's claim.

ARGUMENT

I. DISPUTED ISSUES OF FACT WITH RESPECT TO SCIENTER PRECLUDE SUMMARY JUDGMENT.

To establish FCA liability, Ven-A-Care must prove that Abbott "knowingly or recklessly cheated the government." *United States ex rel. Taylor-Vick v. Smith*, 513 F.3d 228, 232 (5th Cir. 2008); *see also Hindo v. Univ. of Health Scis. / Chi. Med. Sch.*, 65 F.3d 608, 613 (7th Cir. 1995) ("The requisite intent is the knowing presentation of what is known to be false. In short, the claim must be a lie.") (internal quotation and citation omitted). Flawed reasoning and even "[taking] advantage of a disputed legal issue" arising from vague provisions or regulations cannot support liability under the FCA. *See Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478-79 (9th Cir. 1996).[8] Courts (including this one) have recognized that this rigorous

[8] *See also United States ex rel. Rose v. E. Tex. Med. Ctr. Reg. Healthcare Sys.*, No. 2:05 CV 216, 2008 WL 4056601 at *5 (E.D. Tex. Aug. 25, 2008) (granting summary judgment to defendant because plaintiffs could not prove scienter under the FCA where both parties had reasonable interpretations of an ambiguous regulation); *United States ex rel. Kersulis v. Rehabcare Group, Inc.*, No. 4:00-CV-00636, 2007 WL 294122 at *4 (E.D. Ark. Jan. 29, 2007) (granting summary judgment to defendants, finding that plaintiffs had not produced adequate evidence of

scienter inquiry is highly fact intensive and therefore not ordinarily amenable to summary judgment. *See, e.g., Massachusetts v. Mylan Labs.,* 608 F. Supp. 2d 127,154 (D. Mass. 2008); *see also United States ex rel. Koch v. Koch Indus., Inc.,* 57 F. Supp. 2d 1122, 1130 (N.D. Okla. 1999) ("[T]he 'knowingly' prong of the FCA is one of fact, and should be decided by the finder of fact at trial and not prematurely decided on summary judgment.").[9] This case is no exception.

First, the List Prices and WACs on the Erys were and are actual prices, which Abbott PPD set for legitimate business reasons having nothing to do with third-party reimbursement. (*See* § C, *supra*.) There is no evidence that Abbott set prices to create, maintain, or grow a spread on Ery products. To the contrary, the List Prices and WACs on these products were only increased five times during the fourteen-year claims period, and only then to keep pace with inflation. (SOAF ¶ 16.) Indeed, the spread actually *shrunk* over time as PPD was able to raise the contract prices. (*Id.* ¶ 5.)[10]

Second, Abbott PPD reported the List Prices and WACs because the employees understood that the compendia were requesting those prices, and the compendia never suggested that this reporting practice was wrong. (SOAF ¶ 27.) To the contrary, Red Book specifically instructed manufacturers to submit "WAC pricing," which it defined as a "list price to wholesale distributors [that] does not reflect any deal terms or specialized contract pricing." (*Id.* ¶ 20)

(continued…)

scienter where it was "undisputed that prior to 2002, CMS never issued formal guidance to either the provider community or to fiscal intermediaries").

[9] *United States ex rel. Longhi v. Lithium Power Techs.*, Nos. 08-20194, 08-20306, 2009 WL 1959259 (5th Cir. July 9, 2009), provides Ven-A-Care no support. There, the government established scienter sufficient to satisfy the summary judgment standard through a collection of multiple false statements, which included "egregious[]" "lie[s]" and purposefully and recklessly misleading statements. *Id.* at *5, *10. The defendants were found to have "blatantly deceived" the government. *Id.* at *11.

[10] Ven-A-Care's assertion that "list prices set and reported by PPD for the Ery products . . . did not adjust for decreasing or flat average transaction prices" (VAC Mem. at 20) is just plain wrong; Abbott's "average transaction prices" on the Erys were increasing during the relevant period. (SOAF ¶ 11.)

Abbott complied with these instructions to the letter. Any theory by Ven-A-Care suggesting why Abbott should have known to disregard the compendia's express directives and instead report some other, unsolicited price merely creates an issue of fact. Abbott did not understand WAC or AWP to mean any sort of average of net transactional prices. (*Id.* ¶ 30.) There is no evidence that Abbott PPD employees knew, were told, or had any reason to believe that they were supposed to report prices that were the "best estimate of the prices generally and currently paid by providers for a drug" (VAC Mem. at 5-6 (quoting and citing 42 C.F.R. § 447.301)) — a standard that Ven-A-Care raises, but which applied only to (but was not even followed by) the states, not manufacturers that were reporting certain actual prices to public compendia for multiple uses. (SOAF ¶ 31.)

Ven-A-Care certainly cannot show that Abbott's failure to do so constitutes a reckless disregard of the law. There was no law directing manufacturers to report any sort of average market price to the compendia, and no one told Abbott to report such a number. (SOAF ¶ 26 (Ven-A-Care's expert, Marmor, conceding that AWP was never defined).) *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, 460 F. Supp. 2d 277, 285 (D. Mass. 2006) (independent expert concluded that "inconsistent and ambiguous information exists even currently concerning what type of price AWP measures"). The *only* law instructing manufacturers to report an average price was the law regarding AMP, 42 U.S.C. § 1396r-8(k)(1), and there is no dispute that Abbott complied with this instruction – reporting its average manufacturer's prices for the Ery products directly to the government quarterly throughout the claims period. (*Id.* ¶ 26.) This fact alone raises a disputed issue sufficient to defeat summary judgment: how could Abbott PPD have had the necessary scienter to defraud the government when it was reporting to the

government the very average discounted net prices, in the form of AMPs, that Ven-A-Care claims that Abbott should have been reporting.[11]

Third, there is, at best for Ven-A-Care, a genuine dispute of material fact surrounding Ven-A-Care's allegation that Abbott marketed the spread on Ery products. Every Abbott witness denied doing so, and their testimony stands unrebutted. Ven-A-Care's backstop theory that the spread "marketed itself" is not only unsupported by any facts, but it is also non-sensical when one considers the state Medicaid programs' widespread use of MACs and FULs to cap payments for erythromycins. With such caps in place, having a higher AWP spread literally made no difference to providers, who would receive the same payment regardless of whether one generic had a higher AWP. Thus, there was no advantage to market. (SOAF ¶ 46.) Even Ven-A-Care's expert Matthew Perri acknowledged the futility of marketing the spread for such drugs. (*Id.* ¶ 53.)

Ven-A-Care's remaining arguments do no more than confirm the existence of disputed issues of material fact, and they can be dispatched in short order:

- *"Megaspreads."* This Court has already rejected Ven-A-Care's argument that the mere size of the spreads is sufficient to establish scienter. *Mylan*, 608 F. Supp. 2d at 137-38, 153-55 (denying summary judgment on scienter even though defendant's products had so-called "megaspreads"). Moreover, viewed in dollar terms, as opposed to percentages, the spreads on the Ery products (generally in the range of $3 per prescription) can hardly be considered "megaspreads." Instead, these small-dollar spreads are well within the range of what the state programs expected (SOAF ¶ 82), less than the spread needed and used by the states to compensate pharmacies for the insufficient dispensing fees (*see §* F(2), *infra*), and less than other spreads that this Court has exempted from liability.

[11] Ven-A-Care protests that AMPs were not disclosed to the state Medicaid programs, but the enabling statute provided that the state Medicaid programs could get the AMP data, and the U.S. government alone chose not to send the AMP data to the states. (SOAF ¶ 26.) If the government truly believed that it had to keep manufacturers' average prices confidential or that manufacturers' were demanding this, the government cannot legitimately claim that the manufacturers understood or should have understood that they were obligated to make this same pricing information publicly available by reporting it to the compendia. This point, alone, raises a factual dispute that precludes summary judgment on the falsity and scienter elements.

- *Rebate Agreement*. Ven-A-Care's reliance on Abbott entering the Rebate Agreement is misplaced. There is no reason why agreeing to pay rebates to lower state Medicaid programs' costs obligated Abbott to become knowledgeable about all aspects of the Medicaid system. The opinions that Ven-a-Care cites would require Abbott to know the legal requirements associated with complying with the Rebate Agreements (e.g., Calculating AMPs), not how each state calculated payments on all Abbott products. Ven-A-Care's citing the agreement is ironic since it was pursuant the Rebate Agreement that Abbott reported to the U.S. government its AMPs, which reflected the "actual transaction prices" that Ven-A-Care claims the government wanted. (SOAF ¶ 26 (Ven-A-Care's own expert conceding that submitting AMPs would have satisfied his definition of AWP).) Indeed, the Rebate Agreements' existence shows that states and the federal government were well aware of, and acquiesced in, the spreads. After all, Medicaid rebates were instituted precisely because the states knew that they were paying providers far more than their acquisition costs. The rebates allowed the states to continue paying premiums (the spreads) to providers to further policy goals and then to offset those payments by demanding rebates from the manufacturers. Abbott, therefore, has already paid for the Ery spreads through the rebates. Abbott then paid for them again when many states enacted supplemental rebate requirements. Now, Ven-A-Care is seeking another payment (and treble damages and penalties) through this lawsuit.

- *HPD Practices*. Ven-A-Care improperly attempts to import into this case evidence collected in a separate action relating to Abbott's HPD – a division that was always separate from PPD and was divested entirely from Abbott in 2004. In particular, Ven-A-Care makes reference to HPD's Home Infusion Services department and to a price adjustment that HPD made to its products' List Prices in 2001 These matters do nothing to illuminate or advance this case. Home Infusion Services was not even slightly connected to PPD, and there is no evidence linking Home Infusion's experience with Medicaid payments to PPD's operations.[12] Similarly, the HPD 2001 price adjustment had nothing to do with Ery or any other PPD product. The entire effort is therefore immaterial and inadmissible in this case. (Fed. R. Evid. 401, 403, 407.)[13]

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[12] Ven-A-Care claims that there was "substantial overlap and migration of employees between HPD and PPD." (VAC Mem. at 19.) That is not true, and Ven-A-Care's cited statement of fact does not support the assertion. Furthermore, Ven-A-Care fails to show that any person "migrating" from HPD to PPD carried relevant knowledge about Medicaid and supplied that information to anyone in PPD responsible for setting or reporting prices. Ven-A-Care only refers to two employees who worked in PPD after working in HPD's Home Infusion (VAC SOF ¶ 34), and it is implausible to charge low-level employees such as April Gerzel (an employee working with claims processing and customer support with Home Infusion (VAC Thomas Ex. 35 at 6:25-8:18) or Donna Arnold (an administrative assistant and customer representative with Home Infusion with no responsibility for reimbursement claims (VAC Thomas Ex. 8 at 10-30)) with that knowledge. In fact, Ven-A-Care deposed both of those employees and learned that they did not have that knowledge. (VAC Thomas Ex. 35 at 8:19-9:13; VAC Thomas Ex. 8 at 15, 23, 30.)

[13] Furthermore, Ven-A-Care should be judicially estopped from arguing that actions by HPD are material to this case. Ven-A-Care opposed a motion to dismiss that was based on the FCA's first-to-file bar by arguing that the case about the Erys is totally different than the case about the HPD products. (Dkt. # 4912.) Similarly, Ven-A-Care should be estopped from arguing that the subpoenas to Abbott in 1997 and 2000 "pertaining to its HPD list price reporting" (VAC Mem. at 9) are material to this case about the Erys.

- *Medicare Working Group.* The short-lived Medicare Working Group (a study group that existed for about a year and generally tracked Medicare legislation) provides no help to Ven-A-Care. There is no evidence that this group ever considered the Ery products at all or even that any material *Medicaid* payment information emanated from the *Medicare* Working Group.

- *Lupron.*® Ven-A-Care also cites an alleged discussion about TAP's Lupron® product, and then trumpets details of the 2001 criminal settlement relating to that product, but that is a red herring. The Court has consistently recognized that the TAP Lupron® settlement is irrelevant to AWP litigation against Abbott. (*See, e.g.,* 5/16/07 Transcript of Proceedings at 57-62.) It is certainly not the sort of admissible evidence that the Court may consider to adjudicate a summary judgment motion. *See e.g., Hillstrom v. Best Western TLC Hotel*, 354 F.3d 27, 32 (1st Cir. 2003) ("This evidence was not admissible and could not be considered in the summary judgment analysis."); *Horne v. City of Boston*, 509 F. Supp. 2d 97, 111 n.19 (D. Mass. 2007) (" A court will not consider inadmissible evidence in ruling on a motion for summary judgment.").

- *Government knowledge.* Ven-A-Care argues incorrectly that the government's knowledge or expectations is relevant to scienter only if the government explicitly approved the pricing conduct. Evidence about the industry's and the government's expectations about prices and price reporting are absolutely relevant, and it is clear that a written "hall pass" is not necessary to defeat FCA liability. The government's acquiescence is enough. *See, e.g., United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 682 n.8 (5th Cir. 2003) (recognizing the government's "acquiescence" as "highly relevant" to determining FCA liability). Here, CMS certainly acquiesced in Abbott's reporting undiscounted list prices and in the states' use of the Ery AWPs. In addition CMS knew exactly what it was doing when it approved states' Medicaid payment rates, even permitting EAC formulae with discounts off of AWP that were significantly less than the discounts suggested by OIG reports. (SOAF ¶ 96(a).)[14]

Given the disputed facts highlighted above, there is no basis for the Court to resolve Abbott's scienter as a matter of law.

Because summary judgment must be denied as to the scienter element, Ven-A-Care's entire motion is doomed, and the Court need not even consider the remaining elements of the FCA claims. *See In re: Hartmarx Securities Litig.*, No. 01 C 7832, 2003 WL 22757748, at *6 (N.D. Ill. Nov. 20, 2003). Even if the Court considers Ven-A-Care's other arguments, its request for summary judgment on those elements fails.

[14] Ven-A-Care argues that the OIG's "guidelines" issued in 2003 disproves government approval, but the guidelines state that they are not intended as a rule and that they did not create any "new law or legal obligations." (RSOF ¶¶ 137-138.) Moreover, even given this chance, the OIG still did not define AWP. (*Id.*)

II. ISSUES OF FACT WITH RESPECT TO FALSITY AND VEN-A-CARE'S FAILURE TO ESTABLISH A "FALSE OR FRAUDULENT CLAIM" PRECLUDE SUMMARY JUDGMENT.

A. The Issue Of Falsity Cannot Be Resolved By Summary Judgment.

Given the record that the parties have developed in this case, a jury could (and, Abbott believes, will) find that the List Prices and WACs that Abbott PPD reported and the AWPs set by the compendia were not "false or fraudulent" under the FCA. This issue should not be resolved on summary judgment.

Ven-A-Care's argument for summary judgment on the falsity element rests on the theory that, although Abbott PPD did not set AWPs on the Erys, it had some knowledge (as did everyone else) of a mathematical relationship between the Erys' WACs reported by Abbott and the AWPs set by the compendia, and therefore Abbott PPD should have overridden its independent business reasons for setting WACs and instead created and reported other (in fact false) WACs that would have resulted in AWPs that reflected some empirical average of wholesale prices, even though the compendia did not request such pricing and the government did not define AWP that way. Neither this theory nor the disputed record of facts entitles Ven-A-Care to summary judgment.

First, a fully developed record of the market's expectations (including the government's expectations) is relevant to, indeed determinative of, falsity, and in this case precludes summary judgment for Ven-A-Care. *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, No. 08-1056, __ F. 3d __ (1st Cir. Sept. 23, 2009) ("*Astra-Zeneca*"); *In re Pharm. Indus. Avg. Wholesale Price Litig.*, No. 08-1002, __ F. 3d __ (1st Cir. Sept. 29, 2009) ("*J&J*"); *Southland Mgmt.*, 326 F.3d at 682 n. 8 (Jones, J. concurring) (government knowledge "is also bound up with whether the claim itself was false"). This Court, acting as factfinder in a bench trial, previously examined third-party payors' expectations to establish a 30% "expectations yardstick" or "speed limit" for

spreads on branded, single-source drugs. That ruling was based on the plaintiffs' expert's opinion that expressly did not apply to generic, multi-source drugs. The First Circuit recently affirmed the decision, ruling that the particular evidentiary record supported the Court's finding of liability where a manufacturer's spreads were outside the "yardstick" imposed by the Court. *Astra-Zeneca*, slip op. at 31, 46-60 (referring to the "yardstick" as a potential liability trigger").

Although the First Circuit's decisions did not address the FCA specifically, its insistence on an analysis of payors' expectations is, if anything, even more vital in the FCA context. The FCA is a punitive statute, and a finding of liability carries with it treble damages and enormous statutory penalties. As one would expect given the high stakes, Congress and the courts have uniformly recognized that the FCA does not impose strict liability for all actions that meet some rigid checklist of factors uniformly applicable in every case. Instead, plaintiffs must *prove* every element, starting with the requirement that the claim at issue is actually false. And in the context of these AWP claims, the federal and state payors' expectations bear directly on falsity. Put simply, if a claim is submitted by a provider for payment of a drug based on AWP, and the payor understands and expects that AWP includes a certain margin over the actual price that the provider paid for the drug (the "expectations yardstick"), then the claim cannot be false as long as it falls within the range of expectations.[15]

This Court has not established an "expectations yardstick" for generic, multi-source drugs, including the Erys. As the First Circuit held in the *J&J* opinion, the Court may not adopt its 30% yardstick from another context involving another type of drug, particularly when in the

[15] To not apply the expectations analysis in this case would mean that a plaintiff could impose the FCA's punitive penalties in situations where the evidence would not even support a finding of common law fraud or deceptive practices (which carry far less drastic sanctions). Indeed, Ven-A-Care's argument would effectively require this Court to find that the very same conduct of the defendants who were found not liable in Track 1 (because the spreads on their branded products fell within the expectations yardstick the Court established) would have supported the imposition of punitive sanctions and treble damages under the FCA (where, urges Ven-A-Care, no yardstick applies). That would turn the law on its head.

other case the Court was acting as the factfinder in a bench trial and did not have to construe the evidence in the light most favorable to defendants. *J&J*, slip op. at 7-8. Here, summary judgment would be inappropriate because Ven-A-Care presents no evidence, much less undisputed evidence, about the Medicaid program's expectations with respect to Ery price spreads. *See id.* at 8 (A "characterization of the district court's decision to adopt the 30% potential liability trigger as 'legal' (and therefore outside the purview of the jury) fails to account for the fact that the creation of the 30% trigger depended on factual findings relating to the relevant expectations as to the size of spreads.").

There is no doubt, however, that the government, armed with OIG and other government reports and Abbott's AMPs, expected that the spreads on the Erys (and other generic drugs), at least on a percentage basis, would be substantially greater than the branded drugs' spreads and would certainly encompass the spreads about which Ven-A-Care complains in this case. (*See, e.g.*, SOAF ¶¶ 66-67 (1992 Congressional hearing record showing Ery spreads of 300% and higher); *id.* ¶¶ 68 (1997 OIG report showing spreads of AWP-42.5% for generics); *id.* ¶ 78 (2002 OIG Report "Medicaid Pharmacy Additional Analysis of the Actual Acquisition Cost of Prescription Drug Products," finding that multisource drugs with established FULs were purchased at AWP-72.1%); *id.* ¶ 82(g) (CMS "Review of Medicaid Drug State Plan Amendments," reporting that "actual acquisition cost of generic prescription drug products nationally is an average of AWP less 65.93 percent")[16] The jury will have to determine what CMS and the state Medicaid programs expected for the multi-source Ery drugs at issue. The

[16] Although Ven-A-Care argues that "it is ridiculous to expect the government to have examined every Abbott product for price discrepancies" – an assertion with which Abbott disagrees and that raises a genuine issue of material fact – certainly it is not "ridiculous" to expect HCFA/CMS to examine and pay attention to reports by its own OIG and other government entities showing large spreads on multi-source pharmaceuticals generally and spreads equal to the spreads about which Ven-A-Care complaints on the Ery drugs specifically. (SOAF ¶¶ 62, 65-68.)

jurors certainly will want to consider that those reports showed spreads equal to and in some cases even larger than the spreads about which Ven-A-Care complains in this case. The issue should not be resolved on summary judgment, and indeed cannot be, given Ven-A-Care's failure to proffer any evidence that the government expected Ery spreads to be non-existent or smaller than they actually were and the plentiful evidence that the government indeed expected spread on the Erys similar to the spreads alleged in the Complaint. *See Bruno & Stillman. Inc. v. Globe Newspaper Co.*, 633 F.2d 583, 597 (1st Cir. 1980) ("falsity appears to be a jury issue"); *Croce v. General Elec. Co.*, Case No. 83-238-G, 1998 WL 6582, *3 (D. Mass. Jan. 7, 1998) ("The truth or falsity of those statements is a question of fact for the jury.").

Second, although Abbott recognizes this Court's reluctance to revisit its decision to take a plain-meaning interpretation of AWP in another matter, the factual record has developed immensely since the Court made that ruling. In particular, the parties now have the benefit of extensive discovery undertaken against the federal and state governments, which the DOJ blocked in the Track 1 case by asserting the Touhy regulations. The evidence now plainly shows that *no one* – not HHS, not the state Medicaid programs, and not the industry – ever believed or set any payments based on the idea that AWP represented an actual average of wholesale prices. Instead, everyone understood AWP to be an undiscounted sticker price that, especially for generic products, bore no predictable relationship to actual market prices. (*See, e.g.*, SOAF ¶ 55 (c) (Tom Scully, CMS Administrator, conceding that AWP was not an actual price and was in fact like "air"); *id.* ¶ 55(d) (Charles Booth, former Director of HCFA's Office of Payment Policy conceding that he never understood AWP to be a calculated average of wholesale prices); *id.* ¶ 55(e) (Elizabeth Richter, former Acting Director of the Center for Medicare Management noting that no HCFA/CMS administrator thought that published AWPs represented the average price at which wholesalers sold drugs to their customers); *id.* ¶ 55(f) (Larry Reed, Technical

Director, CMS Medicaid Division of Pharmacy, agreeing that AWP was like a "sticker price" and was referred to as "ain't what's paid"); *id.* ¶ 80(z) (Tenn. Medicaid rep. testifying that AWP was a nondiscounted list price, not a real price to pharmacies); *see also id.* ¶ 61.) At a minimum, there are factual disputes regarding what AWP (an undefined term) actually meant. These disputes preclude summary judgment on falsity; if the term AWP is interpreted as Abbott, other manufacturers, and indeed the government actually understood it (not as an actual average price, but rather as an undiscounted list price that included margins for providers), then the compendia AWPs and any claims submitted for payment based on such AWPs are not false.

Similarly, this Court cannot summarily adjudge as false under the FCA the WACs submitted by Abbott for its Ery products. As this Court has recognized, WAC was undefined during much of the claims period. *In re Pharm. Indus. Avg. Wholesale Price Lit.*, No. 06-11337-PBS, Mot. Hrg. at 45 (D. Mass. Oct. 20, 2009). Abbott and others in the industry understood it to mean an *undiscounted* list price to wholesalers. (SOAF ¶ 23.) The government certainly never defined it otherwise; in fact, when the government finally did define WAC as part of the Medicare Modernization Act in 2003, it codified Abbott's view. (*Id.* ¶ 21.) This is completely consistent with the instructions that Red Book gave in 1995, when it asked manufacturers to report WACs and defined WAC as "the manufacturer's quoted list price to wholesale distributors [that] does not reflect any deal terms or specialized contract pricing." (*Id.* ¶ 20.) The WACs, sent by Abbott pursuant to these instructions and accurately reported, cannot be considered false.

Third, the law recognizes that there can be no falsity where, as here, the underlying legal obligations were ambiguous. *See, e.g.*, *United States ex rel. Walker v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349, 1357-58 (11th Cir. 2005) (summary judgment reversed because ambiguous regulation created issue of fact whether medical clinic filed false Medicare claim); *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999)

("[D]ifferences in interpretation growing out of a disputed legal question … are not false under the FCA."); *United States ex rel. Ramadoss v. Caremark, Inc.*, No. SA-99-CA-00914-WRF, 2008 WL 3978086, at * 14 (W.D. Tex. Aug. 27, 2008) ("Because of this existing legitimate disagreement over the broad and imprecise language of the Medicaid, HIS, and VA statutes, Caremark's application of restrictions pursuant to its clients' plans does not subject it to FCA liability."); *United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742 (N.D. Tex. 2003) ("[T]his evidence shows that it was unclear what products could be billed under code E0277 and that the defendants' use of code E0277 for the ROHO mattress overlay was not false or fraudulent ….").

There was no law or regulation defining AWP. This Court, the First Circuit, this Court's independent expert, and Ven-A-Care's expert have recognized that AWP is undefined and ambiguous. (SOAF ¶ 26.) In addition, there was no law or agreement with the government compelling Abbott to report any pricing whatsoever to the compendia. (*Id.*) Abbott did so voluntarily, and it did so according to the compendia's express instructions. (*Id.* ¶ 20.) Ven-A-Care cannot claim summary judgment by asserting, years later, that – absent any legal requirement or guidance – Abbott should have known to report prices other than those the compendia requested, and indeed that its failure to do this is a fraud punishable by treble damages and penalties.

Finally, Ven-A-Care's additional factual assertions merely highlight issues of fact. For example, Ven-A-Care argues that Abbott's sales prices "were a fraction" of the reported WACs "creating Mega-Spreads" (VAC Mem. at 13), but that assertion is wrong. For several Ery NDCs, the Base Deal Price was the same as the WAC, and for most others the difference was in the 2% to 30% range. (SOAF ¶ 9.)

B. Ven-A-Care Has Not Established A "False Or Fraudulent" Claim As Required By The FCA.

Furthermore, regardless of whether Ven-A-Care could prove that Abbott PPD's published prices were "false," Ven-A-Care fails to establish a "false or fraudulent claim," which is an essential element of both Section 3729(a)(1) and Section 3729 (a)(2). 31 U.S.C. § 3729(a).[17] Recent law has clarified this point.

The Complaint references two types of claims: the pharmacies' Medicaid "claims for payment" for Abbott's Ery drugs; and the "claims" submitted "by each state to officers and employees of the United States for FMAP [Federal Matching Assistance Percentage]." (Complaint at ¶¶ 32, 37.) Ven-A-Care has failed, however, to point to anything false or fraudulent in either type of claim. The pharmacies' claims included information about the patient, the prescription (including the NDC for which the claim is made and the amount of the drug dispensed), the prescribing doctor, the pharmacy and the pharmacies' usual and customary charge for that NDC, but nothing relating to the reported prices at issue. (SOAF ¶ 97.) Likewise, the States' FMAP claims (CMS Forms 37 and 64) simply contain a line item for a state's total quarterly expenditures for all drugs, including both ingredient costs and dispensing fees. They also did not contain the allegedly false reported prices, and there is no evidence that any state's combined expenditures for any quarter, "in the aggregate" were overstated. Indeed, even after being made aware of these cases, CMS's 30(b)(6) designee testified that, even today, he is not aware of any evidence that states were paid more than permitted by the federal regulations. (*Id.* ¶ 98.)

[17] Even if Ven-A-Care need only show a false statement material to a false or fraudulent claim for liability under 31 U.S.C. § 3729(a)(2), Ven-A-Care still must establish a false or fraudulent claim.

If a claim's statements are literally true, then FCA liability cannot be imposed. *United States ex rel. Milam v. Regents of Univ. of California*, 912 F. Supp. 868, 883 (D. Md. 1995) (granting motion for summary judgment against relator who alleged that defendants had cited studies with falsified results in grant application where application accurately cited studies). It does not matter if the claims are premised on fraudulent conduct. *See, e.g., United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995); *United States ex rel. Debra Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 64 (D.D.C. 2007).

In *Hockett*, a case that the court has not previously considered for this point, the relator alleged that the defendant-hospital engaged in a fraudulent scheme to increase its base rate for Medicare reimbursement. *Id.* at 33. Because a hospital's first-year operating costs under the Medicare program would become its base rate for future years, the hospital tried to inflate its costs by recruiting sicker patients and keeping some patients hospitalized longer than necessary. *Id.* at 32-33. The court held that the claims were not false because the Medicare claims forms accurately stated the amount of time that the patients stayed in the hospital and the services that the patients received. *Id.* at 63. The court rejected the relator's argument that the claims were rendered false by the hospital's underlying fraudulent conduct. *Id.* at 64; *see also id.* at 71 ("The FCA is not a catch-all anti-fraud provision; it only goes after claims that are false, not claims that are submitted while fraud is afoot.").

Like the Medicare forms in *Hockett*, the claims in the present case are not false and, therefore, are not actionable under the FCA. This Court's decision in the California Medi-Cal case does not suggest a contrary result. *See In re Pharm. Industry Average Wholesale Price Litig.*, 478 F. Supp. 2d 164, 173 (D. Mass. 2007). In that case, the Court denied, in part, defendants' motion to dismiss, finding that the relator had made a reasonable allegation of falsity. *Id.* at 173. As the Court acknowledged, however, under California law, unlike the federal FCA,

an underpinning of fraud is sufficient to state a claim. *Id.* at 172 (citing *City of Pomona v. Superior Court*, 107 Cal. Rptr. 2d 710 (Cal. Ct. App. 2001)). Federal FCA law, on the other hand, specifically requires a false claim in order to impose liability and does not apply to claims submitted while fraud is afoot. *Hockett*, 498 F. Supp. 2d at 71; *see also United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 15 (D. Mass. 2008) ("Evidence of an actual false claim is the *sine qua non* of a [federal] False Claims Act violation."); *Rivera*, 55 F.3d at 709. Other rulings on motions to dismiss are also inapposite because the Court afforded plaintiffs the opportunity to show that over-payments were "an intended consequence of the alleged scheme of fraud" which Ven-A-Care cannot prove here. *United States ex. rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc.*, No. 01-12257-PBS, slip op. at 6-7 (D. Mass May 8, 2007) (denying motion to dismiss to allow proof that overpayments were "intended consequence of the alleged scheme of fraud"); *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, 478 F. Supp. 2d 164, 175 (D. Mass 2007). And again, the Court had not considered all of the authority raised in this motion.

III. VEN-A-CARE HAS NOT ESTABLISHED MATERIALITY OR CAUSATION.

A. The FULs And MACs For The Erys Were Not Based On Abbott's Reported Prices.

Ven-A-Care's materiality and causation arguments hinge on its claim that the "Medicaid payment data confirms that [payments for Ery claims were] at levels pegged to or affected by the inflated AWPs." (VAC Mem. at 16.)[18] Ven-A-Care's cited statements of fact, however, do not

[18] Asserting that "the factual premises are intertwined" (VAC Mem. at 15), Ven-A-Care discusses materiality and causation together. It then provides only the standard for materiality, citing the recent amendment to the FCA found in the Fraud Enforcement Recovery Act "FERA" 31 U.S.C. § 3729(b)(4), Pub. L. No. 111-21, §4(b)(4). This reliance on FERA, however, is contrary to a recent case out of the District Court for the District of Columbia, which held that the FERA amendments did not apply retroactively to cases pending at the time of amendment. *U.S. v. Science Applications Int'l Corp.* , --- F. Supp. 2d ---, 2009 WL 2929250, at *14 (D.D.C. Sept. 14, 2009). Because the standard for causation is significantly higher, whether Ven-A-Care has met the materiality

support the claim, and it simply is not true. In fact, the Medicaid payments for the Ery drugs were almost always based on FULs or MACs and *not* on allegedly inflated AWPs. (SOAF ¶ 38, 43, 50.) The FULs were supposed to be set based on the generic equivalents' lowest reported price, which never was the AWP for Ery. (*Id.* ¶ 39.) In addition, CMS and the states often disregarded all reported prices and based FULs and MACs on invoices provided by pharmacies, direct surveys of pharmacies, wholesaler catalogs and price lists, and negotiations with providers. (*Id.* ¶¶ 43, 49.) Thus, there can be no colorable claim that Abbott's reported List Prices and WACs (even if one could consider them "false") were actually material to any Medicaid claims or caused the alleged overpayment.

Recognizing these problems with its main argument, Ven-A-Care resorts to two weak alternatives. First, it states that whether "payment levels may have been affected by a state MAC or another price other than [Abbott's] reported AWPs or WAC . . . is only a damages issue, to be resolved at trial." (VAC Mem. at 17.) Not so. The States' widespread use of payment benchmarks that were entirely divorced from Abbott's allegedly false prices bears on essential elements of FCA liability, such as materiality and causation, and is an issue that must be considered by the jury. Second, Ven-A-Care argues that, had Abbott reported lower prices, those lower prices would have formed the basis of payment for states which used a "lower-of" methodology. The Court already has rejected this very argument, and rightly so. *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F. Supp. 2d at 180. (Ven-A-Care apparently misses this point when it cites the California decision for the proposition that there can be causation "where the reimbursement *is calculated based on* the [allegedly inflated] prices." (VAC Mem. at 17

(continued…)

standard – and discussing merely the "potential to influence" the Medicaid payments – becomes meaningless when Ven-A-Care is attempting to tackle causation at the same time.

(emphasis added).) Indeed, the entire premise of Ven-A-Care's case – that Abbott reported allegedly inflated prices in order to provide a kick-back to its customers and increase its market share – makes no sense in this context. (*See* SOAF ¶ 53.) Ven-A-Care's theory collapses when a state does not base reimbursement on the reported price, such as when a state sets a MAC or the federal government sets a FUL. Under that scenario, Abbott could not increase its market share by manipulating reported prices. And in any event, Ven-A-Care has no evidence concerning how, if at all, Abbott's allegedly inflated prices impacted the MAC and FUL levels set by the state and federal governments. (*Id.* ¶¶ 43-46; 49-50.) Consistent with its prior orders, the Court should not allow recovery of damages for any claims paid based on something other than a compendia-reported price. *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F. Supp. 2d at 180.

Even if the Medicaid programs had used the reported prices or AWP, a jury would want to consider why the programs, with the federal government's approval, did not adjust the formulas for calculating Estimated Acquisition Cost to reflect the discounts reflected in OIG reports sent to the states. (SOAF ¶ 82.) As the next section shows, this consideration is highly factual and disputed, and precludes summary judgment.

B. The Medicaid Programs, With The Federal Government's Full Knowledge And Approval, Knowingly Used Ingredient Cost Payments To Meet Policy Goals.

Ven-a-Care also cannot establish causation given that the government permitted states to use AWPs, to use discounts off of AWPs that were far less than the discounts suggested by OIG reports, and to pay ingredient costs higher than average actual transaction costs in order to meet other requirements and policies, including maintaining Medicaid patients' access to pharmaceuticals equal to the general population's access, compensating pharmacies for

inadequate pharmacy dispensing fees (i.e., cross-subsidization), and providing incentives for pharmacies to dispense generics.

The reimbursement rates that each state Medicaid program used were the result of deliberate policy choices among these components, driven by negotiations with, and sometimes legal action by, pharmacy groups.[19] State Medicaid officials also testified that they understood that their state payment methodologies for drugs methodologies resulted in the payment of a margin on ingredient cost which was used to offset perceived inadequacies in dispensing fees.[20] Several State Medicaid programs established their state payment methodologies for drugs were designed to allow the payment of a margin on ingredient cost to encourage the dispensing of generic drugs. (*See, e.g.*, SOAF ¶ 96 (testimony that states used margin on generic payments to encourage providers to dispense generics).)

Significantly, Ven-A-Care's own expert admitted that the spread on the Ery drugs, as he calculates it, averages about $3 per prescription. (SOAF ¶ 90.) That amount is less than what is universally recognized as the inadequacy of Medicaid programs' dispensing fees to cover pharmacies' dispensing costs. (*Id*.) Ven-A-Care cannot now seek to recover the amount that the Medicaid programs knowingly and strategically used to meet their own policy objectives.

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[19] *See, e.g.*, SOAF ¶ 81(i) (New Hampshire and pharmacies negotiated reimbursement change to AWP-12% in 1996); *id*. at ¶ 81(e) (Arkansas set reimbursement methodology formula as a result of political considerations and "provider relations issues," such as opposition from industry lobbying and concerns by those in the pharmaceutical industry); *id*. at ¶ 81(j) (Alaska's decisions regarding reimbursement rates limited the extent to which the "political realities" allowed the state enough "political capital to force through a change.").

[20] *See, e.g.*, SOAF ¶ 94(b) (by 1994 Delaware Medicaid officials were aware that dispensing fees were inadequate to cover providers' costs for dispensing drugs, but knew that providers were being adequately compensated by margins in the ingredient cost portion); *id*. at ¶ 94(e) (Florida Medicaid realized its dispensing fees were inadequate and that, as a result, pharmacies would "have to have some margin on the ingredient cost of the drug to offset that."); *id*. at ¶ 94(m)(New Jersey's representative testified that "it's entirely permissible for States to use the estimated acquisition cost, the ingredient cost portion to compensate pharmacists for inadequate dispensing fees.").

CONCLUSION

For the reasons stated above, this Court should deny Ven-A-Care's motion for partial summary judgment.

Dated: November 2, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Tara A. Fumerton, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES INC.'S RESPONSE TO VEN-A-CARE'S MOTION FOR PARTIAL SUMMARY JUDGMENT to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 2nd day of November, 2009.

/s/ Tara A. Fumerton
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